The title is amended in response to the requirement set forth in the Office Action.

Claims 27-31 are cancelled in view of the restriction requirement, as being directed to a non-elected invention. Claims 32-39 remain pending. Applicants appreciate the examination of claim 39 along with claims 32-38.

Double Patenting Rejections

Claim 39 is rejected "under the judicially created doctrine of double patenting over claims 16-18 of U.S. Patent No. 5,480,981". The Office Action asserts that patented claims 16-18 "encompass and are coextensive with" present claim 39, "in that they are drawn to portions of the purified CD30-L polypeptide of SEQ ID NO:6, 8, 19, or 23 which bind to CD30".

The enclosed terminal disclaimer is submitted to overcome this rejection of present claim 39. As set forth in the terminal disclaimer, U.S. Patent 5,480,981 and the present application are commonly owned.

The following further discussion of this rejection of claim 39 is presented to insure accuracy of the record. The rejection is not a "same invention-type" double patenting rejection. Applicants are not certain what is meant by "coextensive with" as used in the Office Action. Applicants wish to point out that claim 39 is not identical in scope with claim 16, 17, or 18 of USP 5,480,981.

To illustrate, patented claims 16 and 18 specify that the CD30-L fragments are soluble. Present claim 39 encompasses but is not limited to soluble polypeptides. Claim 39 includes longer fragments of CD30-L that are membrane bound, for example. Patented claim 17 is directed to CD30-L proteins capable of binding CD30, wherein the protein is full length or is a CD30-L having at least one of the recited alterations in the amino acid sequence. Pending claim 39 encompasses CD30-L fragments that are not required to have any of the amino acid sequence alterations.

The terminal disclaimer is submitted in order to speed allowance of the subject claims. Submission of this terminal disclaimer does not indicate agreement with the double patenting rejections or descriptions of relative claim scope as set forth in the Office Action.

Further, Applicants do not concede that the facts of the present application are analogous to the facts of *In re Schneller* (158 USPQ 210) with respect to this or the following double patenting rejection. However, a terminal disclaimer is an acceptable remedy for a non-statutory double patenting rejection, whether for an obviousness-type double patenting rejection or the so-called "non-obvious type" represented by *In re Schneller.* Since the outcome and the remedy acceptable to the PTO (i.e., a terminal disclaimer) are the same,

further discussion of the nature and basis for the non-statutory double patenting rejections does not appear to be necessary.

Claims 32, 34, 35 and 38 are rejected "under the judicially created doctrine of double patenting over claim 20 of U.S. Patent No. 5,480,981". The enclosed terminal disclaimer is submitted in order to obviate this rejection.

For the sake of accuracy of the record, Applicants wish to comment on the statement in the Office Action that the subject matter of present claims 32, 34, 35 and 38 is "covered by" claim 20 of USP 5,480,981. Patented claim 20 is directed to the recited soluble CD30-L/Fc fusion protein (whether or not the fusion protein is a component of an oligomer). The oligomers encompassed by present claims 32, 34, 35 and 38 include but are not limited to oligomers comprising soluble CD30-L/Fc fusion proteins. Thus, some embodiments of the presently claimed oligomers comprise soluble CD30-L/Fc fusion, but other embodiments of the presently claimed oligomers do not comprise the soluble CD30-L/Fc fusion protein recited in patented claim 20.

The Examiner correctly notes that soluble CD30-L/Fc fusion proteins recited in patented claim 20 can form dimers. For complete accuracy of the record regarding the subject matter of claim 20, Applicant notes that claim 20 does not require the recited fusion protein to be part of an oligomer. Claim 20 would encompass the fusion protein in monomeric form as well (monomeric due to the presence of a reducing agent that inhibits disulfide bond formation and thus inhibits dimerization, for example).

Claims 32-39 are rejected "under the judicially created doctrine of obviousness-type double patenting over claims 1-16 of U.S. Patent No. 5,753,203". The "currently claimed soluble protein and oligomers are obvious over the claims of the patent".

The claims of USP 5,753,203 are directed to conjugates that comprise a diagnostic or therapeutic agent attached to a CD30-L polypeptide or oligomer. A copy of a restriction requirement received in U.S. application serial no. 08/225,989 (grandparent of the present application) is enclosed. "Protein conjugates" (Invention IV) were restricted out from CD30 ligand "protein and fusion proteins" (which are in Invention I). Thus, the US PTO made a determination that conjugates comprising diagnostic/therapeutic agents are patentably distinct from CD30-L proteins and fusion protein.

The enclosed restriction requirement appears to support a position that the PTO has deemed the subject matter of present claims 32-39 to be patentably distinct from the conjugates of patented claims 1-16. The Examiner is respectfully asked to consider whether the present double patenting rejection of claims 32-39 may be withdrawn.

Rejection under 35 U.S.C. §112 ¶2

Claims 32-38 are rejected under 35 U.S.C. §112, second paragraph. The Office Action states that claim 32 is indefinite because "the claim does not clearly indicate that the fragments have binding function, merely that the oligomer as a whole have CD30 binding function". Claims 33-38 "are rejected for depending from an indefinite claim".

Claim 32 has been amended in order to enhance the clarity thereof. This amendment is believed to obviate the Examiner's concerns, and to render claim 32 allowable, along with dependent claims 33-38.

Withdrawal of each rejection, and allowance of claims 32-39, are respectfully requested. If any issues remain, the Examiner is invited to telephone the undersigned representative of the Applicants, to discuss resolution thereof.

Respectfully submitted,

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CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date indicated below.

Date: January 13, 2000 Signed: Camilla C. Edwards

Applicant's Copy

Part III: Attachment to Notice of Allowability

Restriction Requirement:

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-21, drawn to DNA, vectors, expression, protein and fusion proteins, classified in Class 435, subclass 69.4, 69.7 and 320.1, Class 530, subclass 350, and Class 536, subclass 23.51.

II. Claims 22-23, drawn to antibodies, classified in Class 530, subclass 387.9.

III. Claim 24, drawn to oligonucleotides, classified in Class 536, subclass 24.5.

IV. Claims 25-26, drawn to protein conjugates, classified in Class 530, subclass 402+.

V. Claims 27-30, drawn to a method of delivering substances to cells, classified in Class 424, subclass 185.1, Class 514, subclass 883 and Class 436, subclass 501.

VI. Claim 31, drawn to a method of treatment, classified in Class 514, subclass 12.

The inventions are distinct, each from the other because of the following reasons:

The DNA and vectors of Invention I and antibodies of Group II are distinct chemical products which are independent, as the products of the two groups are each not required for the manufacture or use of the other.

The expression method of Group I is distinct from Group II wherein the antibodies of group II are neither necessary for nor produced by the method of Group I.

The proteins of Invention I are related to the antibodies of Invention II by virtue of being the cognate antigen, necessary for the production of the antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because the protein can be used another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right as evidenced by claim 31, or to assay or purify the cognate receptor, or in assays for the identification of agonists or antagonists of the receptor protein.

The oligonucleotides of Invention III are related to the nucleic acids of Invention I by virtue of being subsequences of longer disclosed sequences. However, these inventions are

patentably distinct because they are used in materially different processes which processes are completely different and distinct. The arts of antisense therapy and detection of sequences via hybridization are separate and distinct from recombinant production of proteins, as the former requires search and consideration of administration and dosage, as well as substantial other consideration regarding modification of the nucleic acids for particular use as therapeutic agents, such as via chemical derivitization or coupling to other moieties such as ribozymes, or alternatively of specificity and hybridization conditions. Because of the different intended uses for the claimed nucleic acids and different compositions of such and different required areas of such based upon the intended uses, the inventions are regarded as distinct.

The vectors, method and proteins of Invention I are independent and distinct from the oligonucleotides of Invention III, wherein each does not require the other.

The DNA, vectors, expression method and fusion protein of Invention I are independent and distinct from Invention IV, wherein each does not require the other.

The protein of Invention I and conjugates of Invention IV are distinct products, which although related by the inclusion of a common peptide, are nonetheless distinct, as the compositions have different properties and means of use.

The methods of Inventions I and V are independent methods of using distinct products for different purposes. The method of Invention V is distinct from each of the products of Invention I, as Invention V does not utilize nor produce any of the aforementioned products.

The DNA, vectors, method and fusion protein of Invention I are independent and distinct from the method of invention VI, wherein Invention VI does not require any of the above.

The protein of Invention I is related to Invention VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case the product as claimed may be used to make the antibodies of invention II.

The product of invention II is distinct and unrelated to each of inventions III-VI, wherein